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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,006	12/03/2003	James D. Castillo	INVAT-098A	4499
7590	08/24/2005		EXAMINER	
Kit M. Stetina STETINA BRUNDA GARRED & BRUCKER Suite 250 75 Enterprise Aliso Viejo, CA 92656			ALI, SHUMAYA B	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 08/24/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,006	CASTILLO ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-21 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>detailed action</u> . |

DETAILED ACTION

Response to Amendment

1. The amendment to the claims filed on March 8, 2005 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1-3,5-8,10-12, and 17 under **35 USC § 102 (b) and claims 4,9,13,15,19,and 20 under Claim Rejections - 35 USC § 103 (a)** have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

3. The indicated allowability of claims 14 and 21 are withdrawn in view of the newly discovered reference(s) to Young US 5,997, 493. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bledsoe US Patent

4,463,751

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5. **As to claim 1, Bledsoe discloses** a hinge system for stabilizing the human knee which stimulate the movement of the human knee and which can be utilized to restrict the range of motion of the knee to any desired range (see col.1 lines 5-9) having: a flexion-extension regulating device (see fig.5 reference objects 42 and 44) having an upper member (see fig.5 reference object 42) and a lower member (see fig.5 reference object 44) attached to each other in a manner defining a gap (as depicted in fig.5, 2 members inherently defines a gap when the strut 12 is disposed between the member), the there between for accommodating the end portion of the upper strut (see fig.4 reference object 12 with end portion located near reference objects 34 and 36); an elongated main slot (see fig.5 reference objects 60) formed through the upper and lower members and providing a fixed boundary for prescribing a range of motion (see col.4 lines 1-14, 51-54); and a motion limiting member (see fig.5 reference object 68) connectable (see fig.5, connectable via reference object 46) to the end portion of the lower strut (see fig.4 with end portion located near reference objects 40 and 38), the motion limiting member having a motion limiter (see fig.5 reference objects 70 and 72) disposed within the main slot which is caused to move there along (see col.4 lines 18-27) when the upper and lower struts pivot about the knee joint wherein confinement of the motion limiter within the fixed boundary ensures that the knee joint flexes and extends within the prescribed range of motion (see col.4 lines 18-31, col.14 lines 39-45), however does not disclose the member being pivotally connected to the lower member and further being pivotally connectable to the end portion of the lower strut. The limitation is taught by Young US 5,997, 493; Young teaches a hinge for use in an orthopedic brace with second hinge member/locking plate (fig.3, 1008) ("motion limiting member"), where the plate having a projection/flange (fig.3, 1088) which prevents relative movement of the hinge member in a given direction once the projection contacts limiting means situated in an arcuate slot (fig.3, 1038) (col. 2 lines 55-65). Additionally teach the flange is movable ("pivotable") (the flange inherently considered to move along the

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arcuate path in order to abut stop means 1068, 1066, see also col.7 lines 30-36) along the arcuate slot, and one end of the plate is connecting to a strut via rivets (fig.1, 106-108). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the motion limiting member of Bledsoe in view of Young in order to provide a pivotable member which is connected to the lower member and further connected to the lower strut for the purposes of preventing relative movement of the hinge system in a given direction

6. **As to claim 2, Bledsoe discloses** the hinge system of claim 1 wherein the knee brace is a post-surgical knee brace (see col.1 lines 13-18).

7. **As to claim 3, Bledsoe discloses** the hinge system of claim 1 wherein the regulating device and the motion limiting member are each fabricated from metal (see col.4 lines 46-47).

8. **As to claim 4, Bledsoe does not disclose** the hinge system of claim 1 wherein the upper and lower members are unitarily formed to each other. However, a close review of the specification suggests that the applicant does not establish criticality regarding the construction of the upper and lower members being unitarily formed to each other. Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to construct the upper and lower member as one unit or a separate unit because they are considered obvious design choice.

9. **As to claim 5, Bledsoe discloses** the hinge system of claim 1 wherein the upper member comprises an upper body having a generally arcuate configuration (see labeled fig.5).

10. **As to claim 6, Bledsoe discloses** the hinge system of claim 1 wherein the lower member comprises a lower body having a configuration sized and configured to substantially correspond with the end portion of the upper strut (see labeled fig.5)

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11. **As to claim 7, Bledsoe discloses** the hinge system of claim 1 wherein the elongated main slot is curved (arcuate) (see col.3 lines 42-45).

12. **As to claim 8, Bledsoe discloses** the hinge system of claim 1 wherein the upper member comprises an elongated upper slot (see fig.5 reference object 60 formed within 42) and the lower member comprises a elongated lower slot (see fig.5 reference object 60 formed within 44), the upper and lower slots being substantially aligned with each other to form the elongated main slot (a main slot will inherently be defined when the 2 members are aligned according to the assembly lines of figure 5).

13. **As to claim 9, Bledsoe discloses** the hinge system of claim 1 wherein the prescribed range of motion is between about 0 to about 140 degrees (see col.8 lines 50-64). However, Bledsoe discloses that the hinge may be adjusted to permit movement through any limited range of motion (see col.4 lines 39-42). Therefore, Bledsoe's hinge is capable of providing 0-140 degrees of motion. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to adjust the limiting rage of Bledsoe's hinge for the purposes of providing a patient with a desired range of motion including 0-140 degrees.

14. **As to claim 10, Bledsoe discloses** the hinge system of claim 1 wherein the motion limiting member has a motion limiting body (see labeled fig.5) with a first motion limiting surface the motion limiter extending outwardly in a generally perpendicular relationship with respect to the first motion limiting surface (motion limiter 70 and 72 are perpendicularly disposed in the motion limiting member and extends from the second motion limiting surface to the first motion limiting surface and further extended to be engaged with in the slots 58 and 60 as depicted in fig.5 following the proper assembly lines),

15. **As to claim 11, Bledsoe discloses** the hinge system of claim 10 wherein the lower member has a lower body with a second lower surface (see labeled fig.5), the first motion limiting surface being connected

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to the second lower surface (see fig.5 connected via reference objects 70,72, and 46) in a manner as to align the motion limiter within the elongated main slot.

16. **As to claim 12, Bledsoe discloses** the hinge system of claim 10 wherein the motion limiter is a flange (dictionary definition of a flange is a protruding rim, edge, rib, or collar, as on a wheel or a pipe shaft, used to strengthen an object, hold it in place, or attach it to another object. Pin 72 is protruding edge engaged in slots 60 as depicted in fig.2 is inherently capable of holding the reference objects 42 and 44 in place. Therefore, the pin 72 is considered a flange portion of the motion limiting member 66, see fig.5) fabricated from metal (see col.4 lines 46-48).

17. **As to claim 13, Bledsoe does not disclose** the hinge system of claim 1 further comprising at least one stop member removably disposed within the elongated main slot for adjusting the prescribed range of motion. **As to claim 13, Young teaches** a hinge with movement limitation for use in orthosis, orthopedic splints and braces employed at the knee with one hinge member having a limiting mean, pusher (see fig.1 reference objects 1066 and 1068) which is selectively lockable in variable incremental positions by means of engaging teeth and a second hinge member having a projection which prevents relative movement of the hinge members in a given direction once the projection contacts the limiting means (see col.2 lines 60-65). Young additionally teaches the first member has two limiting means variably disposed and releasably secured (reading the limitation "removably disposed") (see col.3 line 52) on either side of the projection (see col.2 lines 66-67), where one controls extension and the other control flexion of the knee (see col.3 lines 45-47). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the hinge mechanism of Bledsoe in view of Young to provide the hinge mechanism with stop members on either side of the projection/flange for the purposes of further limiting the flexion and extension of the knee when the flange contacts the stop members.

18. **As to claim 14, Young teaches** an orthopedic hinge system as stated in claims 1 and 17 above, with two releasably securable stop means (fig.1, 066,1068) which are considered fictionally engaged between radial teeth (fig.1, 1044) of the arcuate member allowing desired range of angular motion. Since the applicant stated on page 19, 0045 that "the stop member. May be fabricated from any rigid or semi rigid material such as plastic, metal and the like", the stop member as disclosed by Young would considered to meet the material construction limitation as well. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the stop member of Bledsoe in view of Young for the purposes of allowing desired range of angular motion of the hinge system.

19. **As to claim 17, Bledsoe discloses** a knee brace comprising an upper pair of struts (see fig.1 reference object 12 on the lateral and medial sides of the knee) and a lower pair of struts (see fig.1 reference object 14 on the lateral and medial sides of the knee), the upper pair and the lower pair being peaceable in an inverted relative orientation above and below the knee joint (see fig.1 reference objects 12 and 14 seems to be disposed in an inverted orientation above and below a hinge 10), with end portions of the upper pair (see fig.2 reference object 12 with end portion near reference objects 34 and 36) and the lower pair being disposed laterally on opposite sides of the knee joint (see fig.2 reference object 14 is disposed opposite side of a knee joint 10); and a hinge system (see fig.2 reference object 10) having a flexion-extension regulating device (see fig.5 reference objects 42 and 44) engaged to the upper strut (see fig.2 reference object 12 is engaged to the hinge via reference objects 36,34 and 56), the device having an elongated main slot (see fig.5 reference objects 60) formed there through and providing a fixed boundary for prescribing a range of motion (see col.4 lines 1-14, 51-54); and a motion limiting member (see fig.5 reference object 68) engaged to the device (see fig.5, engaged via reference object 46) to the respective end portion of the lower strut (see fig.4 with end portion located near reference objects 40 and 38), the

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motion limiting member having a motion limiter (see fig.5 reference objects 70 and 72) disposed within the main slot which is caused to move there along (see col.4 lines 18-27) when the respective upper and lower struts pivot about the knee joint wherein confinement of the motion limiter within the fixed boundary ensures that the knee joint flexes and extends within the prescribed range of motion (see col.4 lines 18-31, col.14 lines 39-45), however does not disclose the member being pivotally connected to the lower member and further being pivotally connectable to the end portion of the lower strut. The limitation is taught by Young US 5,997, 493; Young teaches a hinge for use in an orthopedic brace with second hinge member/locking plate (fig.3, 1008) ("motion limiting member"), where the plate having a projection/flange (fig.3, 1088) which prevents relative movement of the hinge member in a given direction once the projection contacts limiting means situated in an arcuate slot (fig.3, 1038) (col. 2 lines 55-65). Additionally teach the flange is movable ("pivotable") (the flange inherently considered to move along the arcuate path in order to abut stop means 1068, 1066, see also col.7 lines 30-36) along the arcuate slot, and one end of the plate is connecting to a strut via rivets (fig.1, 106-108). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the motion limiting member of Bledsoe in view of Young in order to provide a pivotable member which is connected to the lower member and further connected to the lower strut for the purposes of preventing relative movement of the hinge system in a given direction

20. **As to claim 18, Bledsoe discloses** the knee brace of claim 17 wherein the knee brace is a post-surgical knee brace (see col.1 lines 13-18).

21. **As to claim 19, Bledsoe discloses** the hinge system of claim 17 wherein the prescribed range of motion is between about 0 to about 140 degrees (see col.8 lines 50-64). However, Bledsoe discloses that the hinge may be adjusted to permit movement through any limited range of motion (see col.4 lines 39-42). Therefore, Bledsoe's hinge is capable of providing 0-140 degrees of motion. Therefore, it would have been

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obvious to one of ordinary skills in the art at the time the invention was made to adjust the limiting rage of Bledsoe's hinge for the purposes of providing a patient with a desired range of motion including 0-140 degrees.

22. As to claim 20, Bledsoe does not disclose the hinge system of claim 17 further comprising at least one stop member removably disposed within the elongated main slot for adjusting the prescribed range of motion. **As to claim 20, Young teaches** a hinge with movement limitation for use in orthosis, orthopedic splints and braces employed at the knee with one hinge member having a limiting mean, pusher (see fig.1 reference objects 1066 and 1068) which is selectively lockable in variable incremental positions by means of engaging teeth and a second hinge member having a projection which prevents relative movement of the hinge members in a given direction once the projection contacts the limiting means (see col.2 lines 60-65). Young additionally teaches the first member has two limiting means variably disposed and releasably secured (reading the limitation "removably disposed") (see col.3 line 52) on either side of the projection (see col.2 lines 66-67), where one controls extension and the other control flexion of the knee (see col.3 lines 45-47). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the hinge mechanism of Bledsoe in view of Young to provide the hinge mechanism with stop members on either side of the projection/flange for the purposes of further limiting the flexion and extension of the knee when the flange contacts the stop members.

Claims 15,16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bledsoe, Young and in view of Lamb et al. US Patent 4,523,585

23. As to claim 15, Bledsoe does not disclose the hinge system of claim 1 further comprising an elongated arm member sized and configured to be disposed between the end portions of the upper and lower struts,

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24. As to claims 15 and 21, Lamb et al. teach a knee brace applied to a patient's knee subsequent a fracture of tibia or femur, or after operation on the knee (see col.1 lines 5-7) having a crossed connecting links (see fig.1 reference object 24) having spaced pivotal axes (see fig.1 reference objects 26' and 32') connected to a upper extension link (see fig.1 reference object 12) and a lower extension link (see fig.1 reference object 14) respectively (see col.3 lines 1-5) to allow peculiar motion desired for the knee movement (see col.3 line 13). Additionally, it would have been obvious to one of ordinary skills in the art that a connecting link (24) between two extension links/ struts is capable of holding the two struts in position. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the hinge of Bledsoe in view of Lamb et al. in order to provide the hinge system with a cross connecting link/or elongated arm member for the purposes of allowing peculiar motion desired for the knee movement and holding the upper and lower struts in position.

25. As to claim 15 does not disclose nor Lamb et al. teach the arm member is fabricated from metal. However, it is obviously well known to one of ordinary skill in the art that the braces are constructed from rigid substance such as metal for providing stronger support to the injured body parts.

Specification

26. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: As to claim 4, specification on page 13, lines 4-5,"the flexion-extension regulating device 24 is formed by attaching an upper member 26 and a lower member 28 together" does not provide proper antecedent basis to the claim limitation "unitarily formed to each other".

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27. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: specification does not positively recites "connectable to the lower strut" of claim 1. Disclosure on page 6, 0013 states a motion limiting member is pivotally **connected** ... It is further pivotally **connected** to an end portion of the knee brace's lower strut".

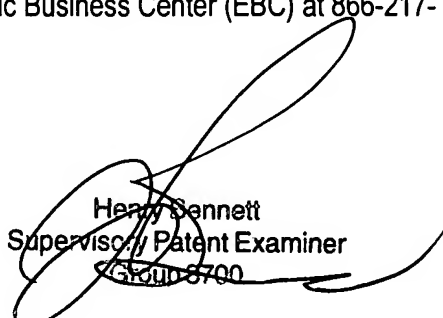
Conclusion

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shumaya B. Ali 8/21/05
Examiner


Henry Bennett
Supervisory Patent Examiner
Group 8700

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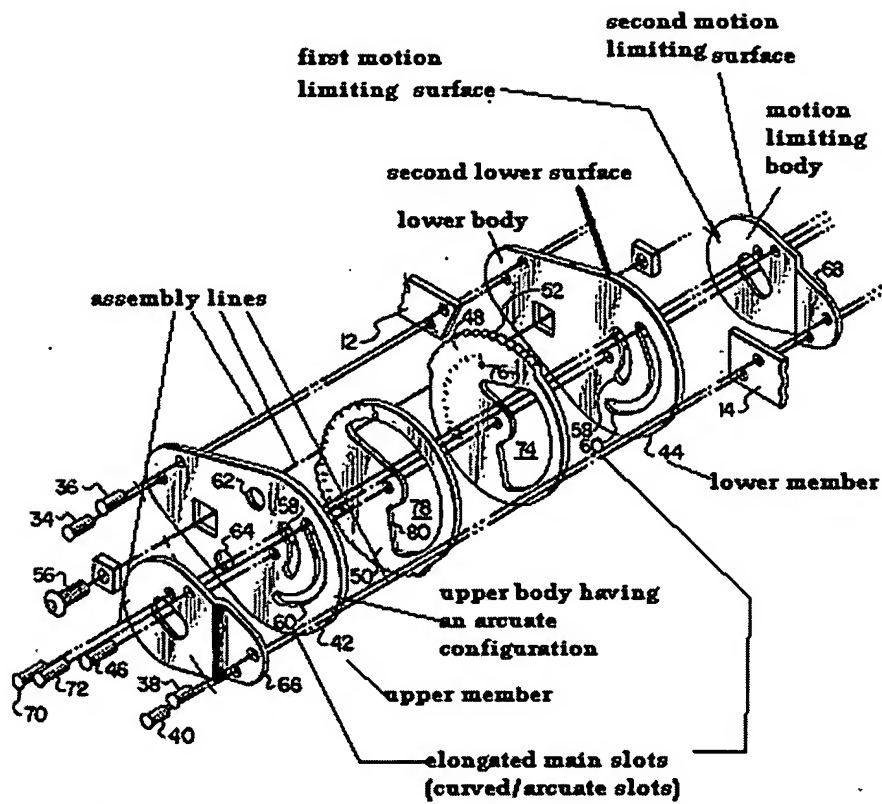


FIG. 5

PRIOR ART
US PATENT 4,463,751
BLED SOE